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10/646,682	08/22/2003	Dennis S. Fernandez	FERN-P013	1019

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Fernandez & Associates, LLP  
PO Box D  
Menlo Park, CA 94026-6402

EXAMINER
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MILLER, MARINA I

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/646,682

Applicant(s)

FERNANDEZ, DENNIS S.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20 pages.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-10) in the reply filed 3/14/2006 is acknowledged.

Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claims.

An action on the merits of claims 1-10 follows.

#### ***Information Disclosure Statement***

Information Disclosure Statements (IDS) filed 12/22/2004, 6/16/2005, and 8/8/2005 have been considered in full. It is noted that two identical IDS's were filed on 7/8/05. One has been considered; all pages of the other have been crossed out to avoid duplication upon printing. The IDS filed 8/22/2003 comprises references which are not properly cited; many references are missing a date of publication and several are missing a place of publication (*e.g.* journal title or publisher's name and city). See MPEP 707.05(a)-(f) and 37 CFR 1.97 and 1.98 for IDS requirements. References which are improperly cited have not been considered and are crossed out. References which have been considered are indicated by the examiner's initials. References cited herein, if crossed out on the IDS, have been properly cited on a Form 892 by the examiner to indicate consideration thereof. Considered references and references cited on Form 892 need not be re-cited on a new IDS. However, if applicants desire consideration of all references, the nonconsidered (crossed out) references must be cited in proper format on a newly submitted IDS.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on p. 48. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

***Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentations is “undue.” These factors include, but are not limited to:

- a) The breadth of the claims;
- b) The nature of the invention;
- c) The state of the prior art;
- d) The level of one of ordinary skill;
- e) The level of predictability in the art;
- f) The amount of direction provided by the inventor;
- g) The existing of working examples; and

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h) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. 858 F.2d at 740. While all of these factors are considered, sufficient amount for a prima facie case are discussed below.

a) The claims are broad because they are drawn to a generic simulation system and method. The simulation system comprises a general sensor for sensing a general biological target and a general simulator which uses an unknown signal and an unknown model to generate a therapeutic or diagnostic output for the unknown trait, disease, *etc.*. The simulation method comprises steps of sensing a general biological target and simulating using an unknown signal and a method. The instant specification does not provide specific guidance to practice the invention because it does not disclose how to generate an unspecified signal by using an unspecified sensor which “senses” an unknown target and how to generate a therapeutic or diagnostic output by using a an unspecified simulator which uses an unknown signal and a model. Without knowing how to generate a signal, what signal is generated, and/or what biosensor is used (*e.g.*, detecting a fluorescent signal), a biological target (*e.g.*, cells, nucleic acids, antibody, *etc.*), how to simulate and what model to use, and/or the goal of the output, generating a therapeutic or diagnostic output would require undue experimentation.

b) The invention is drawn to a simulation system and a method.

c), e) While prior art analysis shows that the diagnosis of different stages, traits, diseases, *etc.*, requires using specific biological materials (*e.g.*, cells, nucleic acids, proteins) that produce specific signals indicative of a disease (*e.g.*, an enzymatic reaction showing differently colored

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signals for different cell stages, an array hybridization producing different fluorescent or radioactive signals for different nucleic acids) and/or using a specific biosensor (*e.g.*, lipid, nucleic acid, cell, metabolite, blood-flow sensors, *etc.*), the instant claims do not recite what biological material is used, what signal is generated, what biosensor is used, and what disease is diagnosed. Prior art analysis also discloses using specific simulation models corresponding to tested conditions (*e.g.*, a model predicting drug absorption parameters). The instant claims do not recite what model is used and/or the goal of the simulation. Thus, without the recitation of the specific conditions in the instant claims, the claims are not enabled by the prior art. *See*, for example, Quellette, Biosensors: Microelectronics marries biology, *The Industrial Physics, News*, p. 11-12, Sept. 1998; Tonnesen, Biosensors, at <http://www.hitl.washington.edu/sci/vw/EVE/I.D.1.c.Biosensors.html> retrieved 5/2/2006; Microarray & protein chips categories, at <http://www.genomicglossaries.com/content/printpage.asp?REF=/content/Microarray>, retrieved 6/27/2003; Fu, US 2003/00084407; Turcott, US Patent, 6,575,912. Grass, US Patent 6,542,858.

Specifically, the prior art of Quellette teaches using specific biosensors (*e.g.*, antibody, enzyme, receptor proteins, lectins, nucleic acids, cells, or tissue sections) for monitoring specific traits (*e.g.*, blood glucose, food contaminants, blood serum antibodies, specific genetic diseases, gene expression, polymorphism, *etc.*) wherein a biosensor produces a specific signal (*e.g.*, thermometric, piezoelectric, acoustic, magnetic, or optical response) (p. 11-12). The prior art of Quellette further teaches enzymatic, antibody, and nucleic acid assays for detecting analytes known to be indicative of genetic disorder, AIDS virus, diabetes, food poisoning, blood diseases, *etc.* (p. 11-12). The instant claims do not recite any specific trait or disease, nor any biomarker

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correlated to a particular trait or condition. The instant claims do not recite any specific biological material, a specific biosensor for testing a specific disease, and/or a specific signal produced by a biosensor.

The prior art of Tonnesen teaches diagnosis and simulation of specific disease (*e.g.*, muscular dysfunction, eye disorder, diabetes) by using specific antibody, ligand binding, and cell metabolism assays (p. 1, 3-4). The prior art of Tonnesen also teaches using biosensors for food quality appraisal and environmental monitoring wherein a biosensor produces a specific signal (*e.g.*, colorimetric or electrical, p. 4). Again, the instant claims do not recite any particular disorder or analyte known to be correlated to a disorder, nor any particular assay for detecting such an analyte.

The prior art of Tonnesen teaches diagnosis of specific diseases and biomarkers which are known to be correlated to a specific disease and specific assays used for the diagnosis (*e.g.*, an antibody array for the detection of 24 disease markers in mouse serum and 84 proteins in human serum; and antigen array for detecting autoimmune diseases; DNA arrays for detecting polymorphism, *etc.*). Again, the instant claims do not recite any particular disorder or analyte known to be correlated to a disorder, nor any particular assay for detecting such an analyte.

The prior art of Fu teaches detecting particular markers that are known to correlate to specific diseases (*e.g.*, cancer, olfactory disorders, metabolic disorder, diabetes, *etc.*) and specific assays for diagnosis (p. 3 and claims 21 and 30). Again, the instant claims do not recite any particular disorder or analyte known to be correlated to a disorder, nor any particular assay for detecting such an analyte.

The prior art of Turcott teaches monitoring heart function with a specific biosensor and detecting a plethysmography signal that is representative of arterial pulse pressure (claim 1). Again, the instant claims do not recite any particular disorder, nor any particular assay for detecting such a disorder.

The prior art of Grass teaches a metabolism and toxicity assays, screening assays characterized by cytochrom P450 form-specific metabolism, gene expression assay, protein assay, and enzymatic assay for detecting specific disorder (col. 33-34). Grass also teaches specific simulations for simulating tested conditions (*e.g.*, gastrointestinal model, metabolic model, col. 20-24). Grass teaches using specific cells for detection of specific disorders (col. 26-28). The instant claims do not recite any particular disorder or analyte known to be correlated to a disorder, nor any particular assay for detecting such an analyte. The instant claims do not recite any particular simulation model corresponding to tested conditions.

d) The skill of those in the art of molecular biology and bioinformatics is high.

f) The specification does not provide any working examples and does not teach how to make and use a system and a method without knowing what sensor to use, what signal is detected, what target is used, and what simulator is used for generating a therapeutic or diagnostic output. In fact, the specification does not teach how to actually diagnose a disease, trait, condition, *etc.* The specification does not teach a system comprising an actual biosensor and a simulator.

h) In order to practice the claimed invention, one skilled in the art must randomly select a sensor and a target and must guess which signal and model to use for generating an unknown therapeutic or diagnostic output. This constitutes undue experimentation.



Due to the undue experimentation required to obtain the goal of the invention, the lack of directions presented in the specification, the complex nature of the invention, and the state of the prior art showing that the diagnosis of different stages, traits, or diseases requires using specific biological materials that produce specific signals indicative of a specific disease and using a specific biosensor, the specification fails to teach one skilled in the art how to use the claimed method for generating diagnostic or therapeutic output.

### *Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 recites “[I]ntegrated biosensor and simulation system.” It is not clear whether claim 1 is drawn to an integrated biosensor, a simulation system, or a system comprising an integrated biosensor and a simulation system. As the intended limitation is not clear, claim 1 is indefinite. Claims 2-5 depend from claim 1, and are therefore also indefinite.

Claim 1 recites the limitation “a simulator for using the signal and a model of the target to generate a therapeutic or diagnostic output.” It is not clear whether a simulator uses a signal and a model wherein the simulator generates a therapeutic or diagnostic output OR whether a simulator uses a signal and a model wherein the model generates a therapeutic or diagnostic

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output. If the former, then it is not clear whether the simulator only uses a signal and a model or it actually generates an output. As the intended limitation is not clear, claims 1-10 are indefinite.

Claim 2 recites the limitation “the sensor is reconfigurable by the simulator.” It is not clear whether the limitation recites the intended use of the sensor and/or the simulator and/or a result. It is also unclear what limitation of the sensor and simulator is intended. As the intended limitation is not clear, claim 2 is indefinite.

Claim 3 recites the limitation “the sensor senses a food material for consumption by the biological target to generate a second signal, the simulator further using the second signal to generate the therapeutic or diagnostic output.” Claim 3 depend from claim 1 which recites a system comprising “a sensor for sensing a biological target to generate a signal and a simulator for using the signal and a mode to generate a therapeutic or diagnostic output.”

It is not clear what further limitation of a *product* of claim 1 is intended by *method steps* (*i.e.*, sensing and using) recited in claim 3 performed by the product.

It is further unclear whether “generating” is an active, positive method step or an intended use of the sensing sensor.

It is further unclear whether the sensor recited in claim 3 senses a biological target which has consumed a food material or it senses only a food material. If this is the latter, then it is not clear what further limitation of claim 1 is intended because a sensor recited in claim 1 senses only a biological target.

It is further unclear whether the sensor of claim 3 generates a second signal only or it generates a second signal in addition to a signal recite in claim 1 (*i.e.*, a first signal).

It is also unclear whether the simulator recited in claim 3 uses only the second signal to generate the output or uses “a signal” as recited in claim 1 (*i.e.*, the first signal) AND the second signal.

It is unclear whether the simulator recited in claim 3 uses only the second signal (without using a model, as recited, for example in claim 1) to generate the output.

As the intended limitations are not clear, claim 3 is indefinite.

Claim 4 recites the limitation “a regulatory condition.” It is not clear what limitation is intended because “a regulatory condition” may mean actual conditions of a sensor/simulator used in experiments (*e.g.*, voltage, current, type of signal, threshold, algorithm, *etc.*), regulation of a biological process in response to stimulation (*e.g.*, regulation of gene expression by a drug), or conditions set up by a regulatory agency (*e.g.*, FDA sets up a threshold or generates a model for the acceptable concentration of a drug, toxin, or bacteria in water, food, organism, *etc.*, according to a safety standard). As the intended limitations are not clear, claim 4 is indefinite.

Claim 4 recites the limitation “the output.” Claim 4 depends from claim 1 which recites “a therapeutic or diagnostic output.” It is unclear which “output” is intended because claim 1 recites two outputs, *i.e.*, a therapeutic or diagnostic output. As the intended limitation is not clear, claim 4 is indefinite.

Claim 5 recite “the sensor couples to the simulator via a programmable switch.” It is not clear whether a sensor is a separate unit which is physically connected to a simulator (*e.g.*, a computer-simulator receives data from a sensor and simulates a diagnostic output using the data

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and a program), a sensor and a simulator are independent units and communicate with each other via a network or an independent computer, sensor and simulator compose one unit (*e.g.*, computer that runs two different programs depending on the stage of the experiment), *etc.*

It is further unclear whether “coupling” is a method step and what limitation of the product, sensor, and/ or simulator recited in claim 1 is intended.

As the intended limitation is not clear, claim 5 is indefinite.

Claim 6 recites “[a]utomated sensor and simulation method.” It is not clear whether claim, 6 is directed to a system (*i.e.*, an automated sensor) which performs the recited method steps OR a method comprising recited steps. As the body of claim 6 recites active method steps (*i.e.*, sensing and simulating), the preamble is interpreted as if it recited a simulation method only. As the intended limitation is not clear, claims 6-10 are indefinite.

Claim 6 recites the limitation “simulating using the signal and a model of the target to generate a therapeutic or diagnostic output.” It is not clear whether simulating using the signal and a model results in generating a therapeutic or diagnostic output OR a signal and a model are used in simulating wherein the model generates a therapeutic or diagnostic output. If the former, then it is not clear whether “generating” is intended to be an active, positive step of the method. As the intended limitation is not clear, claims 6-10 are indefinite.

Claim 7 recites “the method of claim 6 wherein a sensor ... reconfigures a sensor.” It is not clear where the step of “reconfiguring” fits within the method of claim 6. It is further unclear whether “reconfiguring” is intended to be an additional step to “sensing” and “simulating”

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recited in claim 6 or is intended to substitute one or more steps of the method of claim 6. As the intended limitation is not clear, claims 7-10 are indefinite.

Claim 8 recites the limitation “the sensor senses a food material for consumption by the biological target to generate a second signal, the simulator further using the second signal to generate the therapeutic or diagnostic output.” Claim 8 depends from claim 6 which recites “sensing a biological target to generate a signal and simulating using the signal and a mode to generate a therapeutic or diagnostic output.”

It is not clear whether the sensor recited in claim 8 senses a biological target which has consumed a food material or it senses only a food material. If this is the latter, then it is not clear what further limitation of claim 6 is intended because sensing recited in claim 6 senses only a biological target.

It is further unclear whether the sensor of claim 8 generates a second signal only or it generates a second signal in addition to a signal recite in claim 6 (*i.e.*, a first signal).

It is also unclear whether the simulator recited in claim 8 uses only the second signal to generate the output or it uses “a signal” recited in claim 6 (*i.e.*, the first signal) AND the second signal.

It is unclear whether the simulator recited in claim 8 uses only the second signal (without using a model, as recited, for example in claim 6, to generate the output.

As the intended limitations are not clear, claim 8 is indefinite.

Claim 9 recites the limitation “the output.” Claim 9 depends from claim 6 which recites “a therapeutic or diagnostic output.” It is unclear which “output” is intended because claim 6 recites two outputs, *i.e.*, a therapeutic or diagnostic output. As the intended limitation is not clear, claim 9 is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

Claims 1-2, 4-7, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Giuffre, US Patent 6,042,548.

Guiffre discloses a method and a system for registering changes in brain and central nervous system activity by using simulation and a signal (*e.g.*, cardiovascular signal (abstract, claims 1, 5, 7, 8, 12, and 18; col. 4, lines 6-17). Guiffre discloses generating a signal by a biosensor (col. 9, lines 26-37). Guiffre discloses a simulation using a signal and a model (col. 4, line 39 through col. 5, line 11). Thus, Guiffre anticipates claims 1 and 6. Guiffre discloses reconfiguring a sensor by a simulator (*e.g.*, constructing a hybrid signal) (fig. 3 and col. 6, line 53-59), thereby anticipating claims 2 and 7. Guiffre discloses generating the output according to a regulatory condition (col. 7, last paragraph through col. 8, first full paragraph), thereby anticipating claims 4 and 9. Guiffre discloses coupling using a computer and a program (a switch) (fig 1-3), thereby anticipating claims 6 and 10.

Claims 1-2, 4-7, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Grass, US Patent 6,542,858.

Grass discloses a system and a method of pharmacodynamics for studying molecular interaction between a drug and body constituents (col. 1, lines 18-29; fig. 1 and 3). Grass discloses a sensor and data acquisition from a biological target (see Data acquisition, col. 26-34 for different assays and biosensors), a simulator, and a simulation using the signal from a target and a model (fig. 3-4, 9-10, 41-42, 44-46; *see also* col. 18-20 for an input/output and a simulation model). Thus, Grass anticipates claims 1 and 6. Grass discloses reconfiguring a sensor by a simulator (*i.e.*, adjusting, col. 12, line 52 through col. 13, line 32), thereby anticipating claims 2 and 7. Grass discloses generating an output according to regulatory conditions (col. 15, lines 47-66), thereby anticipating claims 4 and 9. Grass discloses using a computer and a program (claims 43 and 63), thereby anticipating claims 5 and 10.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grass, US Patent 6,542,858, as applied to claim 1-2, 4-7, and 9-10 above, and further in view of Quellette, *The Industrial Physics*, pages 11-12, 1998.

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Grass teaches a system and a method of claims 1-2, 4-7, and 9-10, as set forth above.

Although Grass discloses generating a plurality of signals, he does not specifically disclose sensing a food material.

Quellette discloses a plurality of biosensors and using biosensors for different tasks. Specifically, Quellette discloses new regulations requiring more thorough testing food for pathogens. Quellette discloses using a biosensor technology for detecting contaminants in meat, poultry, seafood, fruits, and vegetables (p. 11-12).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and the system of Grass to use biosensors for sensing food for contaminants, such as taught by Quellette, where the motivation would have been to improve identification of microorganisms and food-borne illnesses, as taught by Quellette, p. 11, right col.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Examiner  
Art Unit 1631

MM

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*5/10/06*